REMARKS

Claims 1-7 and 42-47 are currently pending in this application. In the present Office Action claims 1-7 and 42-47 stand rejected under 35 U.S.C. §102(b) and claims 42-47 stand objected to. New claims 48-51 are hereby added; said new claims recasting amended method claim 1 and 2 as a computer readable medium storing instructions for performing the method, and as an apparatus for performing said method set forth as means-plus-function claims, respectively.

Applicant respectfully requests entry of this Amendment, such that claims 1-7 and 42-47 stand amended herein (either expressly or through dependency upon an expressly amended claim).

Applicant hereby confirms the prior provisional election without traverse by Michael C. Soldner of claims 1-7 and 42-47 and acknowledges acceptance of the formal drawings earlier submitted for this application.

I. Claim Rejections Under 35 U.S.C. §102(b)

Claims 1-7 and 42-47 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Pat. No. 5, 749,906 to Kieval et al. ("Kieval"). Applicant respectfully disagrees with the stated basis for rejection for said claims and based upon the amendments tendered herewith and the remarks hereinbelow, asserts that this ground of rejection now stands traversed.

Applicant asserts that a patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987) (emphasis added). Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991).

Patent law nonetheless establishes that a prior art reference which expressly or inherently contains each and every limitation of the claimed subject matter anticipates and invalidates. See, e.g., EMI Group N. Am., Inc., v. Cypress Semiconductor Corp., 268 F.3d 1342, 1350 (Fed. Cir. 2001) ("A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim."); Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.").

Applicant therefore only needs to show a single difference between the asserted anticipatory reference and the presently claimed invention in order to traverse the asserted rejection.

To that end, Applicant respectfully asserts that Kieval fails to possess at least the following elements of the amended claims. First of all, as opposed to the presently claimed invention Kieval does not contemplate, disclose or depict a triple chamber or quadruple chamber pacing engine (i.e., a system or method for use thereof), capable of delivering bi-ventricular pacing therapy. For example, Kieval depicts at FIG. 1 a double chamber pacing system having a medical electrical lead disposed in the right atrium and the right ventricle. Referring now to the Abstract of Kieval clearly illustrates that the object of the system and methods disclosed and/or claimed in Kieval is directed to different subject matter; namely:

> A dual chamber pacemaker is provided having capability for adjusting the AV escape interval so as to optimize the timing of delivered ventricular pace pulses for therapy of patients with cardiomyopathy. The pacemaker system continually monitors to determine when a delivered pace pulse results in a fusion beat, and periodically adjusts the AV escape interval in accordance with the percentage or rate of incidence of such fusion beats. In one specific embodiment, the pacing system determines the percentage of delivered ventricular pace pulses which are followed by fusion beats over a predetermined number of intervals, and decrements AV escape interval when such percentage is not below a predetermined minimum. The pacing system also periodically increments AV escape interval when the rate of fusion beats is acceptable, thereby providing a closed loop system for maintaining the AV interval at an optimally long value consistent with maximizing full capture by delivered ventricular pace pulses. In another embodiment, the V--V escape interval of a non-tracking mode pacemaker is controlled to optimize pre-excitation of the ventricle. (emphasis added.)

Applicant asserts that the "V- -V escape interval" noted above merely refers to the interval between subsequent depolarizations of a ventricle and respectfully suggests that said interval does not relate to a V-V bi-ventricular interval contemplated by the presently claimed invention. Furthermore, Kieval discloses how to control so-called "fusion beats" *to keep them to an acceptably low percentage (e.g. "[t]*he acceptable percentage may be zero, i.e., no fusion beats are acceptable, or it may be a suitable non-zero small percentage." Kieval at Col. 3, ln. 27-30). In contrast, the presently claimed invention relates to controlling pacing therapy for patients suffering from advanced heart failure (HF) and exhibiting cardiac conduction defects to optimize V-V timing during bi-ventricular pacing and *to maximize fusion beats during triggered bi-ventricular pacing* to thereby optimize ventricular synchrony (and cardiac output). Incidentally, the present invention disclosed the advantages of measuring QRS complex duration from the later, or second, ventricular depolarizations for a given cardiac cycle (in a triple or quadruple chamber pacing engine).

As for the relationship of QRS complex duration, the QRS complex duration is measured both acutely and chronically. The maximum duration and minimum duration of discretely measured QRS complex duration values are stored and an average QRS duration value calculated (for a given period of time). The pacing therapy provided according to the presently claimed invention attempts to promote bi-ventricular pacing that minimizes QRS complex duration resulting from the second of two ventricular pacing stimuli (for most HF patients this is typically the LV QRS complex duration). The various values of QRS duration for such triggered bi-ventricular depolarizations over a period of time are believed to strongly correlate to heart failure status, trend, onset, progression and the like.

The fact that Kieval promotes use of far-field R-wave signals (denoted "FFRS" in Kieval) appears to be just about the only common ground between Kieval and the presently claimed invention.

In operation, the presently claimed invention first determines whether or not bi-ventricular pacing is enabled. If not, a pair of electrodes either adapted to couple to the left ventricle (LV) or the right ventricle (RV) deliver a pacing stimulus between said pair

of electrodes. If so, a variety of bi-ventricular pacing modalities are invoked depending on the sequence of sensed triggered or intrinsic depolarizations.

II. GENERAL OBSERVATIONS REGARDING THE AMENDMENT

Applicant acknowledges an inherently limited knowledge of and appreciation for every arguably equivalent structure and/or process for every limitation expressed in the presently pending and amended claims. In addition, Applicant expressly reserves the right to later refute any presumption related to such arguably equivalent structure and/or process and respectfully assert that any such structure and/or process must have been foreseeable at the time the instant application was filed. That is, the literal limitations of the appended claims should not be deemed limited where, as a practical matter, no opportunity to craft any limitations covering an *unforeseen* equivalent structure and/or process.

Any amendment to the pending claims made herein may be attributed to the desire of Applicant to reasonably and clearly state, within the confines of the English language, the subject matter comprising the present invention. As a result, such amendments not directly related to prior art should not be construed as a waiver or disclaimer of any portion of the scope of the claims or an admission that such claims do not cover any particular equivalent structure and/or process unless expressly stated to the contrary herein. For example, a number of amendments tendered herewith relate solely to the desire of the prosecuting attorney to modify certain claims as a matter of personal preference. In addition, Applicant asserts that the claims tendered herewith in fact broaden the scope of the claimed invention and are not intended to narrow the scope thereof.

III. CONCLUSION

In view of the foregoing remarks and amendments, it is believed that the application is now in condition for allowance and Applicant respectfully requests issuance of a Notice of Allowance in due course.

Applicant avers that no New Matter is introduced hereby. Entry and favorable consideration of this Amendment is earnestly solicited so that the claimed subject matter hereof may timely pass to issuance as U.S. Letters Patent.

Respectfully submitted,

Date: 28 August 2003

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